



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,850	04/09/2004	Michael John Dunkley	0198.00	2666
21968	7590	02/22/2007		
NEKTAR THERAPEUTICS 150 INDUSTRIAL ROAD SAN CARLOS, CA 94070			EXAMINER ALI, SHUMAYA B	
			ART UNIT	PAPER NUMBER
			3771	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/822,850

Applicant(s)

DUNKLEY ET AL.

Examiner

Shumaya B. Ali

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13-25, 27, 28 and 31 is/are rejected.
- 7) ☒ Claim(s) 10-12, 26, 29 and 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Allowable Subject Matter***

Claims 10-12,26,29, and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The indicated allowability of claims 1-9,13-25,27,28, and 31 is withdrawn in view of the newly discovered reference(s) to Helgesson et al US 6,892,728B2. Rejections based on the newly cited reference(s) follow.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-9, and 13-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Helgesson et al US 6,892,728B2.**

**As to claims 1,14,19,** Helgesson discloses a handheld aerosolization apparatus (see figs. 1-22) comprising a housing (5) defining a chamber having a plurality of air inlets (38,39), the chamber being sized to receive a receptacle (5) which contains an aerosolizable pharmaceutical formulation; a shield (64 and 22) which covers at least one but not all of the air inlets, whereby

Art Unit: 3771

the shield prevents blockage of the at least one air inlet by a user grasping the apparatus (see fig.15), and an end section (17) associated with the housing, the end section sized and shaped to be received in a user's mouth or nose so that the user may inhale through the end section to inhale aerosolized pharmaceutical formulation that has exited the receptacle (col.5 lines 15-30, col.9 lines 50-67, and col.10, lines 1-12).

**As to claims 2,15, and 20**, Helgesson discloses wherein the shield is a portion of the end section (see fig.15).

**As to claims 3,16, and 21**, Helgesson discloses wherein the end section is removably connected to the housing and wherein the end section may be removed from the housing to provide access to the chamber (see fig.1, col.5 lines 52-67).

**As to claims 4,17, and 22**, Helgesson discloses wherein the shield is a portion of the end section (see fig.15).

**As to claim 5**, Helgesson discloses wherein the shield comprises at least two covering portions (64 and 22), each covering portion covering at least one inlet (shield 64 has air inlets 66, and shield 22 has air inlets 30 and 31).

**As to claim 6**, Helgesson discloses wherein there are two covering portions and wherein the two covering portions are diametrically opposed (see fig.15),

**As to claim 7**, Helgesson discloses wherein the at least two covering portions are separated by open portions (see figs.1 and 15).

**As to claim 8**, Helgesson discloses wherein the open portions provide direct access to at least one inlet (see figs. 1 and 15).

Art Unit: 3771

**As to claim 9**, Helgesson discloses wherein the shield extends longitudinally along the apparatus (see figs. 1 and 15).

**As to claims 13,18, and 23**, Helgesson discloses wherein the inlet is shaped to create a swirling airflow within the chamber (swirling effect is caused by the dispersion 18 and suction 19 chambers).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 24,25,28,29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helgesson et al US 6,892,728B2.**

**As to claims 24,25,28,29, and 31**, Helgesson lacks a detailed description of the claimed steps, however discloses structural limitations required to perform the method steps (see above rejection cited for claims 1-10,13, and 14-23). Thus, the method steps as cited in claims 24,25,28,29, and 31 would have been obvious result of using the apparatus of Helgesson.

Art Unit: 3771

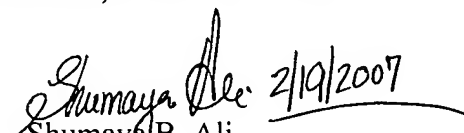
***Conclusion***


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Valentini (US 4,069,819), Voges (5,894,841), and Steil (3,918,451) are cited to show aerosolization apparatus within the scope of claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Shumaya B. Ali  
Examiner  
Art Unit 3771

  
JUSTINE R. YU  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700  
2/2/07